**AMENDMENT** 

In the Claims:

This list of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**:

9.-26. (Cancelled)

27. (New) A sharp instrument and sheath, comprising:

an elongate rod having first and second ends, the first end having a sharp point and an upper

portion defining a first longitudinal axis and the second end having means for connecting

a tube thereto, wherein the second end includes a recess configured to receive an

indexing means of a safety guide for rotationally orienting the elongate rod with respect

to the first longitudinal axis; and

a selectively and longitudinally lockable safety sheath for receiving the first end of the rod.

28. (New) The sharp instrument of Claim 27, wherein the rod is bent such that the second end

defines a second portion and a second longitudinal axis non-colinear with respect to the first longitudinal

axis.

29. (New) The sharp instrument of Claim 28, wherein the recess has a linear axis in a plane

defined by the longitudinal axes.

30. (New) The sharp instrument and sheath of Claim 27, wherein when the sheath is locked onto

the first end of the elongate rod, the sheath is sufficiently elongated so as to substantially cover the sharp

point.

31. (New) The sharp instrument and sheath of Claim 27, wherein the sheath has a locking device

configured to selectively grip a shaft of the sharp instrument, holding the sharp pointed end within.

BLACK LOWE & GRAHAM \*\*\*\*

701 Fifth Avenue, Suite 4800 Scartle, Washington 98104 206,381,3300 • F: 206,381,3301

-2-

- 32. (New) The sheath of Claim 30, wherein the selectively lockable safety sheath includes an annular locking vane defining a circular aperture adapted to receive the first end of the sharp instrument in a first unlocked position and movable to a second locked position.
- 33. (New) A sharp instrument and a safety guide for placing the sharp instrument through the skin of a patient, comprising:
  - a sharp instrument;
  - a first end of a safety guide having a receiver mechanism adapted for lockably accepting a sharp point of the sharp instrument;
  - a second end of a safety guide having a holder mechanism adapted for releasable securing the sharp instrument in all directions; and
  - a guide beam having a linear elongated body and a substantially uniform cross-section along its length, wherein the receiver mechanism and the holder mechanism are guided in continuous linear alignment along at least a portion of the guide beam such that the sharp point of the sharp instrument follows a substantially straight line from within the receiver mechanism to a position apart from the receiver mechanism and back into the receiver mechanism when the safety guide is actuated.
- 34. (New) The sharp instrument and safety guide of Claim 33, wherein the receiver mechanism includes a receiver having an end face defining an open bore-hole; and wherein the safety guide first end further includes a receiver standard fixed to one end of the guide beam and configured to support the receiver, a receiver pin that intersects the receiver and the receiver standard, and a releasable safety sheath having an elongated cylindrical body defining a diameter substantially the same as the bore-hole, such that the safety sheath is releasably insertable into the open bore-hole.
- 35. (New) The sharp instrument and safety guide of Claim 34, wherein the safety guide first end further includes a sheath-retaining pawl having a portion thereof selectively engagable with a notch in the safety sheath so that the safety sheath is selectively removable from the receiver bore-hole.

BLACK LOWE & GRAHAM \*\*\*\*

701 Fifth Avenue, Suite 4800

-3-

36. (New) The sharp instrument and safety guide of Claim 35, wherein the receiver standard also has a protruding ridge vane for activating the pawl, wherein the receiver is rotatable about the receiver standard on the receiver pin, whereby rotation of the receiver about the receiver pin causes the ridge

vane to engage the sheath-retaining pawl thereby releasing the safety sheath from the receiver bore-hole.

37. (New) The sharp instrument and safety guide of Claim 34, wherein the safety sheath includes a

target at an end face of the cylindrical body facing the holder mechanism and defines a round hole

substantially the same diameter as a shaft of the sharp instrument and configured to receive the

instrument point, and further defines a cylindrical interior cavity, wherein the round hole extends

through the target to the interior cavity.

38. (New) The sharp instrument and safety guide of Claim 34, wherein the safety sheath further

includes a positionable locking vane, a compressible sheath spring, and opposing first and second end

faces of the interior cavity, wherein the compressible sheath spring and the positionable locking vane lie

within the interior cavity and are substantially concentric with a longitudinal axis of the interior cavity,

and wherein the locking vane and the compressible sheath spring are interpositioned between the

opposing first and second end faces, and the first end face is non-normal to the longitudinal axis of the

interior cavity so that when the locking vane is pressed against the non-normal first face an interior edge

of the locking vane engages the sharp instrument preventing the removal of the sharp instrument from

the safety sheath.

39. (New) The sharp instrument and safety guide of Claim 38, wherein the first end of the safety

guide further includes a key having a wedge-shaped tip and oriented substantially perpendicular to the

longitudinal axis of the interior cavity so that by inserting the key between the locking vane and the first

end face of the interior cavity, in opposition to a compression force generated by the compressible

sheath spring, the locking vane becomes oriented substantially normal to the longitudinal axis, relieving

interference between the locking vane and the received sharp instrument, whereby the sharp instrument

can be removed from the safety sheath.

BLACK LOWE & GRAHAM \*\*\*\*

-4-

40. (New) The sharp instrument and safety guide of Claim 33, wherein the safety guide first end further includes a key and a thumb press bar configured to engage the key, wherein actuation of the key aligns a locking vane substantially normal to a longitudinal axis of a received sharp instrument, enabling removal of the received sharp instrument from the receiver.

41. (New) The sharp instrument and safety guide of Claim 40, wherein the guide beam further includes a slot and a boot selectively supported by the guide beam and a crickle configured to be

reversibly straightened by actuation of the thumb press bar, wherein by straightening the crickle the

selectively supported boot is advanced into in the guide beam slot, preventing removal of the sharp

instrument from the receiver mechanism when the safety guide is re-closed.

42. (New) The sharp instrument and safety guide of Claim 33, wherein the holder further includes

a groove positioned longitudinal to a second longitudinal axis of the sharp instrument, at least one pair

of holder element levers, each lever having a first and second end, wherein the first end of each holder

element lever is positioned opposite the first end of its pair and with the groove positioned substantially

between the first ends, and a reset lever, wherein at least one element lever of each pair is configured to

pivot on an element lever pivot pin, so that by turning the reset lever the first end of at least one element

lever moves toward or away from the first end of its pair, thereby holding or releasing a shaft of the

sharp instrument.

43. (New) The sharp instrument and safety guide of Claim 42, wherein the holder further includes

a ram and a ram support guide, wherein the ram support guide is configured to enable the ram to slide

longitudinally along an axis common to both the ram and the ram support guide substantially

perpendicular to the groove, an actuator block, wherein the ram is fixed to the actuator block, so that the

actuator block slides with the ram, an actuator spring, wherein sliding of the actuator block is aided by

the actuator spring, and at least one pair of force-multiplying levers, wherein the at least one pair of

force-multiplying levers mechanically couple the actuator block to the second ends of the at least one

pair of holder element levers, and wherein turning the reset lever pivots at least one holder element lever

of each holder element lever pair.

BLACK LOWE & GRAHAM \*\*\*\*

701 Fifth Avenue, Suite 4800 Scartle, Washington 98104 206,381,3300 • F: 206,381,3301

25315

-5-

- 44. (New) The sharp instrument and safety guide of Claim 33, wherein the first end of the safety guide, the second end of the safety guide, and the guide beam are configured to cooperatively guide the point of the sharp instrument into the receiver, placing the sharp instrument safely through the skin of a patient.
- 45. (New) The sharp instrument and safety guide of Claim 44, wherein a safety sheath of the first end of the safety guide is configured to be permanently fixed to the point of the sharp instrument after one placement of the instrument through a patient's skin.
- 46. (New) A method for preventing more than a single use of a sharp instrument without a reset of an accompanying safety guide, comprising:

providing a safety guide, including a holder, a receiver, a guide beam, and a safety sheath, and a sharp instrument;

holding a shaft of the sharp instrument in the holder of the safety guide;

releasing a point of the sharp instrument from the safety sheath of the safety guide by sliding the holder away from the receiver along the guide beam;

returning the point of the sharp instrument to the safety sheath following a surgical operation by sliding the holder back toward the receiver; and

preventing the holder and receiver from being slid away from one another along the guide beam until a reset action of the safety guide is performed.

47. (New) The method of Claim 46, wherein sliding the holder away from the receiver includes: providing a boot, a guide beam slot, a thumb press bar, and a key of the safety guide, supporting the boot above a narrow portion of a guide beam slot;

actuating, by a thumb press bar, a mechanically coupled key to release the point of the sharp instrument from the safety sheath; and

sliding a wide portion of the guide beam slot underneath the boot, reversibly disabling actuation of the mechanically coupled key by permitting the boot to fall into the wide portion of the guide beam slot when the thumb press bar is pressed.

BLACK LOWE & GRAHAM \*\*\*\*

701 Fifth Avenue, Suite 4800 Scattle, Washington 98104 206,381,3300 • F: 206,381,3301

25315

-6-

48. (New) The method of Claim 47, wherein separating the sharp instrument and the sheath from the safety guide includes:

providing a sheath-retaining pawl and a reset lever of the safety guide; releasing the sharp instrument from the holder of the safety guide;

actuating the sheath-retaining pawl, enabling the sheath to be separated from the receiver; and

actuating the reset lever, enabling the holder and receiver to be slid apart from one another.

49. (New) The method of Claim 48, wherein actuating the sheath-retaining pawl and the reset lever includes:

providing a receiver standard, a receiver pin, and a protruding ridge vane at a receiver end of the safety guide and notch in the safety sheath of the safety guide;

rotating the receiver about the receiver pin, causing the protruding ridge vane of the receiver standard to interfere with the sheath-retaining pawl, leading the sheath-retaining pawl to retract from the notch in the sheath;

actuating the reset lever of the safety guide; and pulling the boot of the safety guide from the slot in the guide beam.

50. (New) A method for preventing a point of a sharp instrument from being exposed outside a safety sheath while the sharp instrument is outside the control of a safety guide, comprising:

providing a key configured to release a point of a sharp instrument from a safety sheath;

providing a release lever configured to release the sharp instrument from the holder; and disabling the release lever whenever the point of the sharp instrument is outside the safety

disabling the key whenever the sharp instrument is outside a holder of a safety guide;

sheath.

51. (New) A method for placing a sharp instrument through a patient's skin, comprising: releasably inserting a sharp instrument sheathed in a safety sheath into a receiver of a safety guide;

BLACK LOWE & GRAHAM ~--

701 Fifth Avenue, Suite 4800 Seattle, Washington 98104 206.381.3300 • F: 206.381,3301 releasably securing a shaft of the sharp instrument in a holder mechanism of the safety guide;

releasing the sharp instrument from the safety sheath;

sliding the holder mechanism, including the secured sharp instrument, along a guide beam away from the receiver mechanism of the safety guide;

positioning the safety guide so that the holder mechanism securing the sharp instrument and the receiver mechanism are on opposite sides of the patient's skin;

sliding the holder mechanism, including the secured sharp instrument, along the guide beam toward the receiver mechanism, passing the sharp instrument through the patient's skin; receiving a tip of the sharp instrument in the safety sheath;

releasing the shaft of the sharp instrument from the holder mechanism of the safety guide; and

releasing the safety sheath, including the sheathed instrument, from the receiver mechanism of the safety guide.

BLACK LOWE & GRAHAM \*\*\*\*

701 Fifth Avenue, Suite 4800 Scattle, Washington 98104 206,381,3300 • F: 206,381,3301